FDAMA STAKEHOLDER MEETING

APRIL 28, 1999

Talking with Stakeholders About FDA Modernization

✓ Site: Boston, MA

**Your question/comments will become part of Docket Number: 99N-0386

Fax to: 1-888-361-4011 (on April 28 **only**)

Title (required) ☑ Dr. ☐ Mr. ☐ Mrs. ☐ Ms.

First Name (required) George

Last Name (required) FitzGerald

Organization Diacrin, Inc

Stakeholder Group ✓ stakeholder group you represent

☐ Consumer ☐ Consumer Group ☐ Health Professional ☑ Industry ☐ Association ☐ Other

Center ✓ the center/product area your comments address

☑ Center for Biologics Evaluation and Research
☐ Center for Devices and Radiological Health
☐ Center for Veterinary Medicine
☐ FDA General
☐ Center for Drug Evaluation and Research
☐ Center for Food Safety and Applied Nutrition
☐ Office of Regulatory Affairs

Questions to Stakeholders

Please check the box next to the stakeholder question/s from the March 22, 1999, Federal Register notice which your question/comment addresses.

- ☐ 1. What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?
- ☐ 2. What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?
- ☑ 3. What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?
- ☐ 4. What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?
- ☐ 5. What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?
- ☐ 6. Additional Comments on FDA Modernization Efforts.

YOUR COMMENT/QUESTION

In a Risk/Benefit analysis, the Risk and Benefits are generally well understood. Sometimes, however, a risk(s) is not known, for example as in xenotransplantation. What is the FDA position on unknown risk(s) in the risk/benefit analysis

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